Quality Procedures Manual (QPM)

U.S Army Medical Research Acquisition Activity

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0.0 TABLE OF CONTENTS

0.1 QUALITY POLICY STATEMENT

Quality Policy

The vision of the U.S. Army Medical Research Acquisition Activity (USAMRAA) is to be recognized nationally as an enterprise that is a hallmark of excellence in providing world class acquisition products and related services. This is accomplished through the four guiding principles of our mission statement: Quality Products, Our Customers, Ourselves, and Our Community.

As the Director of USAMRAA, I affirm this commitment and have established a system of total quality management and comprehensive quality assurance standard. We are committed, without exception, to continuous improvement, relentlessly seeking to learn the expectations of our customers and striving to meet and exceed those expectations at every juncture. These efforts will enable us to accomplish the following goals:

1. Provide high quality, timely, customer-focused contracting guidance and acquisition solutions.
2. Provide the customers, both core and non-core, these quality products in support of their global U.S. military missions and national medical research interests.
3. Provide our staff an environment that fosters growth and well being.
4. Provide the community an atmosphere that instills public trust and demonstrates good citizenship.

The entire USAMRAA team will adhere to the policies, procedures, spirit and intent of our quality management and quality assurance systems. We all shall continue to aggressively strive to ensure that customer satisfaction and continuous process improvement are achieved at all times, and in everything we do.

Achieving high quality standards is part of our mission. It is our promise to our customers, to our employees and to our community. We are USAMRAA. We are Excellence in Acquisition.

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Kenneth B. Connolly
Director

0.2 COMPANY BACKGROUND

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is the acquisition arm of the U.S. Army Medical Research and Materiel Command (USAMRMC). We are located at Fort Detrick in Frederick, Maryland. USAMRMC is a subordinate command of the Army Medical Command, located in San Antonio, Texas.

The USAMRAA staff consists mainly of contracting professionals in the Office of Personnel Management (OPM) designated 1102 series. In executing the mission set forth below, USAMRAA personnel solicit, negotiate, award, and administer contracts and assistance agreements in support of a broad spectrum of services, materiel, and research and development efforts. USAMRAA is the conduit through which USAMRMC's demand for goods and services are met.

MISSION

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is committed to providing high quality, timely, customer focused contracting guidance and acquisition solutions to the Commander, U.S. Army Medical Research and Materiel Command (USAMRMC) and to all of our customers who are supporting global U.S. military missions and national medical research interests. We take pride in providing the community an atmosphere that instills public trust and demonstrates good citizenship, and offering our staff an environment that fosters growth and well being.

0.3 AMENDMENT RECORD

This Quality Procedures Manual (QPM) contains only the pages issued by this facility. The Management Representative (MR) will process all authorized changes, inserting amendment pages into the official distribution copies. The MR will see that all down level and/or obsolete pages are withdrawn from use and disposed of to prevent unintentional usage. The QPM is a controlled copy document. The MR maintains the master copy (MC) of the QPM. This MC shall be used as the final authority, regarding the latest revision level and amendment status for the USAMRAA. QPM.

Issue #	Section	Date	Page	Description of Revisions:	Approval
1	All	3/10/00	All	Release Draft of QPM	
2	All	3/14/00	All	Update of QPM	
3	All	5/22/00	All	Update of QPM	
4	All	6/06/00	All	Update of QPM	
5	All	6/09/00	All	Update of QPM	
6	All	12/04/00	All	Update of QPM	
7	All	07/09/01	All	Update of QPM	
8	All	08/3/01	All	Update of QPM	

0.4 GLOSSARY

MR - Management Representative

CIO – Chief Information Officer

AM – Account Manager

QAM - Quality Assurance Manual

QPM – Quality Procedures Manual

MC - Master Copy

USAMRAA – United States Army Medical Research Acquisition Activity

Standard(s) - industry, national and international quality standards and IS0 9002:1994

R&A - Responsibility and Authority

C&QP - Control and Quality Plan

IM&TE - Inspection, Measuring and Test Equipment

HSPP&D - Handling, Storage, Packaging, Preservation and Delivery

IQA - Internal Quality Audits

Executive Management - Those functionaries that are responsible for profit and loss

ERMS – Extramural Research Management System

FAR – Federal Acquisition Regulations

DFARS – Defense Federal Acquisition Regulation Supplement

AFARS – Army Federal Acquisition Regulation Supplement

DODGAR – Defense Grants and Assistance Regulation

USAMRMC-AI – USAMRMC Acquisition Instruction

SPS – Standard Procurement System

PD^2 – Procurement Desktop-Defense

2QP01-01
MANAGEMENT RESPONSIBILITY

1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Element 4.1 of ISO 9002: 1994 Edition – MANAGEMENT RESPONSIBILITIES.

2.0 RESPONSIBILITY AND AUTHORITY

The Director, the Deputy for Business Management, the Deputy for Business Operations, and the Deputy for Business Support have the responsibility and authority for implementing the requirements of this procedure.

3.0 PROCEDURE

Quality Policy

3.1 USAMRAA has collectively defined and documented the Quality Policy. The Quality Policy specifies organizational goals and customer expectations. It exists as the vision statement with supporting principles. The Director has signed the Quality Policy Statement.

3.2 The Quality Policy is understood, implemented, and maintained at all levels of the Activity. The Branch Chiefs are responsible for communicating the quality policy to their employees. Other methods of distributing the quality policy are used as necessary.

3.3 The USAMRAA Strategic Plan, that created the Mission and Vision statements, is located in Appendix B. Further, the Mission and Vision Statements appear on USAMRAA's Home Page and are placed throughout the Activity.

3.4 The FAR/DFARS/AFARS requires annual reviews of procurement activities seeking to evaluate critical processes and interest areas at the Army oversight level. Nonconformities are noted and corrective actions are taken accordingly. The Command PARC chairs a Solicitation and Award Advisory Board that reviews possible nonconformities on individual products and recommends corrective actions to the Account Managers as appropriate.

Responsibility and Authority

3.5 The Deputy for Business Support has compiled and keeps descriptions for all jobs affecting quality. These job descriptions identify the specific duties associated with a job function, the qualifications needed for the job, and the responsibility and authority regarding nonconforming product.

3.6 The performance support form describes specific performance objectives. These forms are maintained by the employees and are updated at a minimum of twice a year.

3.7 An Organization Chart defining the authority and the interrelation of personnel, who manage, perform, and verify work-affecting quality has been compiled and is located at Appendix A.

Resources

3.8 If a supervisor determines a need for additional human resources, the appropriate Deputy is contacted. The Deputy and necessary parties may make decision pertaining to resources as appropriate. If needed, an executive meeting is held with the Director, Deputies, and appropriate advisors. The requirement is discussed at this meeting, and recommendations are made to the Director. The Director will then make the final decision.

3.9 Internal Auditors have received formal training. It is USAMRAA's intention that approximately ten percent of the work force will be trained as internal auditors. Auditor responsibilities, auditor appointment letters and certificates of training are kept on file with the MR.

Management Representative

3.10 The Deputy for Business Management has been appointed as the Management Representative (MR) of USAMRAA. The duties of the MR include:

- Ensuring that a quality system is established, implemented, and maintained in accordance with ISO 9002: 1994. This includes maintenance of the quality manual and ensuring that procedures and work instructions are written in a manner consistent with the requirements of ISO 9002: 1994, the main instruction covering the production of contract products is the

Standard Procurement System. The SPS manual is attached hereto as Appendix C.

- Reporting to management the performance of the quality system for review and as a basis for improvement,
- Identifying opportunities for quality improvement,
- Assuring the effectiveness of corrective and preventative action, and
- Other topics as the MR deems appropriate.

3.11 The MR schedules Management Review meetings with executive management. These reviews determine the effectiveness and suitability of the implemented quality system requirements. The MR, in accordance with 2QP01-02, maintains minutes of these review meetings.

4.0 RELATED DOCUMENTATION

Quality Manual Element 4.1
Management Review Meetings Procedure 2QP01-02
Quality System Procedure 2QP02-01
Corrective and Preventive Action Procedure 2QP14-01
Internal Quality Audits Procedure 2QP17-01
Training Procedure 2QP19-01
Master List of Quality Records
Document Master List
SPS Manual (Appendix C)
Work Instructions Regulations (FAR/DFARS/AFARS)

2QP01-02
MANAGEMENT REVIEW MEETINGS

1.0 PURPOSE AND SCOPE

This procedure complies with the Management Review requirements of Element 4.1 of ISO 9002: 1994 Edition – MANAGEMENT RESPONSIBILITIES.

2.0 RESPONSIBILITY AND AUTHORITY

The Director and the MR have the responsibility and authority for implementing the requirements of this procedure.

3.0 PROCEDURE

3.1 Management Review Meetings are held at least on a quarterly basis, or more often as necessary.

3.2 Meeting attendees must include the Director and the Management Representative (MR). Other individuals may be invited to attend as appropriate. Attendance will be included in the minutes.

3.3 The meeting is chaired by the Director and at a minimum covers the following topics:

- Results of internal quality audits since the previous Management Review Meeting (including opportunities for improvement and observations), discussion of updating the audit schedule as appropriate,
- Review of corrective and preventive actions taken since the previous Management Review Meeting,
- Review Quality Policy Statement and Objectives for effectiveness, and
- Other topics brought to the attention of the MR.

3.4 It is the responsibility of the MR to ensure all elements of ISO 9002: 1994 are covered at least once per year. MR is responsible for preparing each Meeting's agenda in order to ensure that this objective is met. A few elements may be discussed at each meeting.

3.5 The MR shall designate a recorder to take minutes at each meeting. The MR maintains the minutes (4.16).

4.0 RELATED DOCUMENTATION

Quality Manual Element 4.1
Management Responsibility Procedure, 2QP01-01
Quality System Procedure, 2QP02-01
Corrective and Preventive Action Procedure, 2QP14-01
Internal Quality Audits Procedure, 2QP17-01
Master List of Quality Records
Document Master List

2QP02-01
QUALITY SYSTEM

1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Element 4.2 of ISO 9002: 1994 Edition – QUALITY SYSTEM.

2.0 RESPONSIBILITY AND AUTHORITY

The Director, the Deputy for Business Management, the Deputy for Business Support and the Deputy for Business Operations have the responsibility and authority for implementing the requirements of this procedure.

3.0 PROCEDURE

3.1 USAMRAA defines and documents its requirements for quality planning through its annual Corporate Strategic Planning process. This plan addresses goals, strengths, weaknesses, opportunities, threats and the analysis of these attributes. As part of the implementation, the Director charters Strategic Planning Implementation Teams, which are groups charged with oversight planning and implementation of specific functional areas.

3.2 The Strategic Plan is reviewed monthly by another chartered group of managers known as the Board of Directors (BOD). Quarterly progress is shared with the entire USAMRAA organization. Adjustments are made as necessary.

Quality Planning

3.3 The requirements outlined in ISO 9002: 1994 Edition element 4.2.3 are identified in the customer agreements as follows:

- Quality plans, in various forms, are prepared from the SPS system and documented in the SPS Manual (Appendix C).
- Controls, processes, equipment, fixtures, resources, and skills are identified and acquired as needed.
- Applicable documentation for the contracting process, and inspection procedures are in place.
- Quality control and inspection techniques are updated as needed.
- Products are identified throughout appropriate stages.

- Standards of acceptability for all features and requirements, including those subjective in nature, are clarified.
- Quality records are maintained as required by 4.16.

4.0 RELATED DOCUMENTATION

Quality Manual Element 4.2
Master List of Quality Records
Management Review Meetings Procedure, 2QP01-02
Document Master List
Quality System Review Form
SPS Manual (Appendix C)

2QP03-01
CUSTOMER AGREEMENT REVIEW

1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Element 4.3 of ISO 9002: 1994 Edition.

2.0 RESPONSIBILITY AND AUTHORITY

The Deputy for Business Operations, Deputy for Business Support, and the Account Managers have the responsibility and authority for implementing the requirements of this procedure.

3.0 PROCEDURE

3.1 Purchase Requests (PR) are received electronically or hard copy. These documents form the records for contract review.

3.2 Each PR is logged in and separated by branch. An Administrative person assigned to the Deputy for Business Support forwards the PR's for each branch to the appropriate Branch Chief. The Branch Chief assigns the PR to the appropriate Contract Specialist.

3.3 The contract specialist reviews the purchase request and determines the appropriate purchase method and instrument.

3.4 If additional information is needed, the contract specialist will contact the customer.

3.5 Checklists, manuals and other work instructions/regulations are used as appropriate, depending on the type of customer agreement being reviewed.

3.6 If the customer makes changes, the Account Manager or Contract Specialist involves the appropriate personnel to review the changes. If USAMRAA does not agree with the customer's changes, the Account Manager or the Contract Specialist contacts the customer for resolution. All changes and resolutions are documented by the Account Manager or Contract Specialist and become part of the official file.

4.0 RELATED DOCUMENTATION

Quality Manual Element 4.3
Master List of Quality Records
Document Master List
Work Instructions/Regulations (FAR, DFARS, AFARS, DODGAR, AI)
SPS Manual (Appendix C)

2QP05-01
DOCUMENT AND DATA CONTROL

1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Element 4.5 of ISO 9002: 1994 Edition – DOCUMENT AND DATA CONTROL.

2.0 RESPONSIBILITY AND AUTHORITY

The Deputy for Business Management, the Deputy for Business Operations, the Chief, Business Oversight Branch, the Chief, Policy and Quality Assurance Branch**,** and the Deputy for Business Support (for administrative documents) have the responsibility and authority for implementing the requirements of this procedure. (NOTE: Policy documents are of a technical nature. Administrative documents relate to personnel and financial activities.)

3.0 PROCEDURE

3.1 Forms may be found in electronic or hard copy format.

3.2 Newly created forms or changes to forms are coordinated through the Forms Control Officer and with the Information Management Office to be entered into the system.

3.3 Forms that are kept electronically are write protected. Only authorized individuals can make changes or add forms to the system.

3.4 Forms that are not kept electronically have some method of control such as revision date, revision number, etc.

3.5 The on-line forms list and a master forms list allows individuals to ensure they are using the most current revision of documents.

3.6 All documents and data are controlled once the appropriate approval authority approves them.

3.7 The revision status of the Quality Assurance Manual and Quality Procedures Manual can be verified by comparing the issue number or date to the issue number or date listed in the respective manual's amendment record.

3.8 The original Quality Assurance Manual and Quality Procedures Manual exists in hardcopy and electronically. The Deputy for Business Management (MR) is responsible for distributing any changes to these manuals.

Both of these manuals are available to all employees on the USAMRAA Homepage, thus eliminating the need for a controlled circulation list for hardcopies. A revised copy of the manual's amendment record must accompany the change that is distributed. The Deputy for Business Management is also responsible for retrieving any superseded documents and destroying them.

3.9 Quality forms will show the revision status information, (i.e. a revision level or revision date) if possible. There are forms that are supplied to USAMRAA from outside the organization (Department of Defense, etc) that may not have revision dates on them.

3.10 All documents are listed either on the electronic data base, on a master document list, or in a master document book.

3.11 The Deputy for Business Support maintains an Administrative Document Master List.

3.12 All hard copy policy volumes are for reference only and are labeled as such. There are two ways of accessing policy documents electronically. The army website is updated on a daily basis. Information is also available on CD and is updated quarterly. USAMRAA requires all personnel, when in-house, to only pull information from the web. Information from the web is updated daily. Anyone using the CD acknowledges that this information is for reference only.

4.0 DOCUMENT AND DATA CHANGES

4.1 The Deputy for Business Management, the Deputy for Business Operations, the Chief, Business Oversight, or the Chief, Policy and Quality Assurance Branch is responsible for pulling obsolete copies of policy documents and replacing them with the current revisions should these documents exist in hardcopy format. The Deputy for Business Support is responsible for pulling obsolete copies of administrative documents and replacing them with the current versions.

4.2 Obsolete on-line documents are segregated to an archive file or purged out of the system. Hard copy obsolete documents must be marked obsolete if they are not purged.

4.3 The authorized individual who approved the original issue must approve all changes to documents and data. Exceptions to this are permitted when the different approval authority has access to pertinent background information.

4.4 Whenever possible, the nature of a document change is indicated through the issuance of a memorandum by the responsible authority summarizing the changes and an attachment of the final revisions.

4.5 Logos and Accreditation marks shall be controlled/displayed in accordance with the Command Regulation and PJR, Inc. Registration Mark Procedure.

5.0 RELATED DOCUMENTATION

Quality Manual Element 4.5
Document Master List
Master List of Quality Records
USAMRMC Regulation 25-30-1 dtd 28 Jan 2000
Perry Johnson Registration Mark Procedure – PRO-3 dtd Jun 2000

2QP06-01
PURCHASING

1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Element 4.6 of ISO 9002: 1994 Edition - PURCHASING.

2.0 RESPONSIBILITY AND AUTHORITY

The Account Managers, Branch Chiefs, and Contract Specialists have the responsibility and authority for implementing the requirements of this procedure.

3.0 PROCEDURE

Evaluation of Subcontractors

3.1 The Central Contractor Registry is available to all branches and serves as an equivalent to an Approved Supplier List. However, each subcontractor is individually evaluated prior to being used.

3.2 Subcontractors are not awarded a contract if they are not registered with the Central Contractor Registry.

3.3 Past Performance Information Management System (PPIMS) is maintained by the Army and is available on-line. Before awards are made, the PPIMS is checked when appropriate to ensure successful past performance of the selected subcontractor.

3.4 Subcontractors are evaluated using the PPIMS system, when appropriate, as well as, monitoring non-conformances associated with subcontractors. Information in the system is used by the Army to help determine the continuing use of subcontractors.

3.5 The List of Parties Excluded from Federal Procurement and Non-Procurement Programs is checked, electronically or hard copy, to identify those parties listed (debarred) and the appropriate cause and treatment code determining a listed party's status.

3.6 The Account Manager reviews and signs each award to signify approval.

3.7 The Defense Contract Audit Agency or other audit authorities will audit the records and facility of a subcontractor as requested by USAMRAA. Such reports are maintained by USAMRAA in the individual award files.

4.0 Verification of Purchased Product

4.1 On occasion, USAMRAA and/or the USAMRAA customer may verify purchased product at the subcontractor's premises. When this occurs, the method of product inspection and release is specified in the purchasing documents as an approved contract clause which ensures the customer the right to verify product at the subcontractor's premises, prior to final acceptance.

5.0 RELATED DOCUMENTATION

Quality Manual Element 4.6
Approved Supplier List
Vendor/ Subcontractor Evaluation Survey
Master List of Quality Records
Document Master List
Work Instruction/Regulations (FARS, DFARS, AFARS, DODGAR, AI,)
PPIMS Manuals
SPS Manual (Appendix C)

2QP07-01
CONTROL OF CUSTOMER-SUPPLIED PRODUCT

1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Element 4.7 of ISO 9002: 1994 Edition – CONTROL OF CUSTOMER SUPPLIED PRODUCT.

2.0 RESPONSIBILITY AND AUTHORITY

The Deputy for Business Operations has the responsibility and authority for implementing the requirements of this procedure.

3.0 PROCEDURES

3.1 Currently there is no Customer-Supplied Product – if in the future we handle such products (as defined at paragraph 3.1 of ISO 9002:1994) a procedure for handling same will be created.

2QP08-01
PRODUCT IDENTIFICATION AND TRACEABILITY

1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Element 4.8 of ISO 9002: 1994 Edition - PRODUCT IDENTIFICATION AND TRACEABILITY.

2.0 RESPONSIBILITY AND AUTHORITY

The Deputy for Business Operations, Deputy of Business Operations, the Account Managers, the Contract Specialists and the Procurement Technicians have the responsibility and authority for implementing the requirements of this procedure. The Chief Information Officer is responsible for oversight of the electronic systems needed to support the SPS requirements.

3.0 PROCEDURE

3.1 Files are identified according to the Army MARKS system, AR25-400-2(1993).

3.1.1 When a PR or Form 9 is received by the designated representative for the Deputy of Business Support, it is then forwarded to the Branch Chief who assigns the action to a Contract Specialist.

3.1.2 The Specialist gives the PR/Form 9 to the Procurement Technician to establish a file folder.

3.1.3 If the action will result in the award of a grant, the number is obtained from a designated person located in the Business Operations area and entered and traced in ERMS.

3.1.4 If the action will result in the award of a contract, the number is automatically assigned through SPS.

3.1.5 The file is labeled in the following manner:

FILE LABEL: 715k DAMD17-_____
Contractor Name/Grantee Name

3.1.6 The File Cabinet is labeled in the following manner:

FILE CABINET LABEL: 715k Contract/Grant Actions
ACTIVE
PIF after final payment

3.1.7 Charge-out cards are available for placeholders when a file is removed from the file cabinet.

4.0 RELATED DOCUMENTATION

Quality Manual Element 4.8
Master List of Quality Records
Document Master List
AR 25-400-2 (1993**)**
SPS Manual (Appendix C)

2QP09-01
PROCESS CONTROL

1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Element 4.9 of ISO 9002: 1994 Edition – PROCESS CONTROL.

2.0 RESPONSIBILITY AND AUTHORITY

The Deputy for Business Management/MR, Deputy for Business Operations, the Deputy for Business Support, the Branch Chief, and the Account Managers, and the Contract Specialists have the responsibility and authority for implementing the requirements of this procedure.

3.0 PROCEDURE

3.1 The USAMRAA has no manufacturing processes, owns no manufacturing equipment, and does not engage in any special processes.

3.2 The USAMRAA is a contracting office. USAMRAA conducts its core business through engaging in contractual and assistance relationships by procuring products and services for customer/clients.

3.3 All employees are responsible for maintaining a safe and suitable work environment.

3.4 All contracting activities follow the same basic process:

- Receipt of Purchase Request
- Identify Program or Customer
- Review and assignment of Purchase Request or Form 9
- Solicitation of Subcontractors
- Award of contracts and/or Assistance Agreements
- Administration Review of Awards
- Final acceptance by customer
- Close out

3.4.1 Purchase requests are received, reviewed and assigned as per Customer Agreement Review 2QP03-01

3.4.2 Solicitation and awarding of the contract takes place in accordance with various in-house and governmental regulations and instructions. These are found both in hard copy and on line. The regulations and instructions are updated and provided by the government, as they become available.

3.4.3 The guidelines provided in the Federal, Defense, Army and USAMRMC Regulations, Acquisitions Instructions and the DODGAR are followed to perform administrative actions.

3.4.4 Acceptance of product is done by the customer at the end of a contract and documented for close out.

3.5 Work instructions and quality forms are available and accessible.

3.6 The only equipment necessary for USAMRAA'S processes is the computer and other office equipment. This equipment is under a preventive system and is also maintained as needed. The Property Book Officer maintains location and maintenance records. There is an Information Management Office (IMO) that provides technical support services as needed.

4.0 RELATED DOCUMENTATION

Quality Manual Element 4.9
Master List of Quality Records
Document Master List
Work Instructions/Regulations (FAR, DFARS, AFARS, DODGAR, AI)
SPS Manual (Appendix C)

2QP10-01
INSPECTION AND TESTING

1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Element 4.10 of ISO 9002: 1994 Edition – INSPECTION AND TESTING.

2.0 RESPONSIBILITY AND AUTHORITY

The Deputy for Business Management, the Deputy for Business Operations, the Deputy for Business Support, Branch Chiefs, and the Account Managers have the responsibility and authority for implementing the requirements of this procedure.

3.0 PROCEDURE

Receiving Inspection:

3.1 Purchase requests are received electronically and/or hard copy. The Branch Chief/Account Manager/Contract Specialist reviews them for completeness. If incomplete, the customer is contacted verbally or electronically to resolve the issue. If unable to resolve, they are returned to the customer. If resolved, the AM/CS document same for the official file. If customer corrects a returned PR, when corrected, it is returned to the AM/CS who made the finding. Urgent release (4.10.2.3) is not applicable to USAMRAA.

In-Process Inspection:

3.2 Upon successful approval of the requirement, the Branch Chief/Account Manager, or his/her designee, documents it for assignment. The Branch Chief/Account Manager, or the designee, reviews the data for completeness and accuracy. Specific reporting requirements differ for each product. Prior to Final Inspection, the product (based on pre-set dollar thresholds) may be referred to a Solicitation and Award Advisory Board (SAAB) in accordance with the MRMC Acquisition Instruction.

Final Inspection:

3.3 The Account Manager or the designee reviews the award. Prior to issuing to the customer, the Account Manager shall approve the award.

Inspection and Test Records:

3.4 Quality records of the actions noted in 3.1, 3.2 and 3.3 are documented and maintained in the working file as required in 4.16 of the standard.

4.0 RELATED DOCUMENTATION

Quality Manual Element, 4.10
Control of Nonconforming Product Procedure, 2QP13-01
Master List of Quality Records
Document Master List
Work Instructions/Regulations (FAR, DFARS, AFARS, DODGAR, AI)
SPS Manual (Appendix C)

2QP11-01
CONTROL OF INSPECTION, MEASURING, AND TEST EQUIPMENT

1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Element 4.11 of ISO 9002: 1994 Edition – CONTROL OF INSPECTION, MEASURING AND TEST EQUIPMENT.

2.0 RESPONSIBILITY AND AUTHORITY

The Deputy for Business Management/MR has the responsibility and authority for implementing the requirements of this procedure.

3.0 PROCEDURE

3.1 USAMRAA has no manufacturing processes, owns no manufacturing equipment, and does not engage in any special processes and therefore does not utilize any Measurement or Test equipment.

2QP12-01
INSPECTION AND TEST STATUS

1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Element 4.12 of ISDO 9002: 1994 Edition – INSPECTION AND TEST STATUS.

2.0 RESPONSIBILITY AND AUTHORITY

The Deputy for Business Management, the Deputy for Business Operations, the Deputy for Business Support and the Account Managers have the responsibility and authority for implementing the requirements of this procedure.

3.0 PROCEDURE

3.1 Nonconforming product or service is defined as a product or service that is not in compliance with Federal Acquisition Regulations, Department of Defense Federal Acquisition Regulation Supplement, the Army Federal Acquisition Regulation Supplement, and the Medical Research and Materiel Command's Acquisition Instruction or the DODGAR.

3.2 Hard copy contract files will be identified as nonconforming by affixing an appropriate identifier (usually a memo stating the non-conformity) and will be resolved in accordance with 2QP13-01 paragraph 4.0 procedures.

3.3 Nonconforming electronic contract files will be identified by the attachment of a yellow note tab on the electronic version.

4.0 RELATED DOCUMENTATION

Quality Manual Element 4.12
Control of Nonconforming Product Procedure, 2QP13-01
Master List of Quality Records
Document Master List

2QP13-01
CONTROL OF NONCONFORMING PRODUCT

1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Element 4.13 of ISO 9002: 1994 Edition – CONTROL OF NONCONFORMING PRODUCT.

2.0 RESPONSIBILITY AND AUTHORITY

The Deputy for Business Management, the Deputy for Business Operations, the Deputy for Business Support and the Account Managers have the responsibility and authority for implementing the requirements of this procedure.

3.0 PROCEDURE

3.1 Nonconforming files are appropriately identified, but not segregated, because other parts of the process may continue that are unrelated to the breach of procedure.

4.0 REVIEW AND DISPOSITION OF NONCONFORMING PRODUCT

4.1 Issues in everyday procedures are evaluated for severity. The Account Manager of the contract assesses the situation and determines the need for management involvement. Likewise, the Account Manager determines the applicability of the term “Nonconforming Product”.

4.2 In the case of a breach of procedure, the Deputy for Business Management and the Deputy for Business Operations, the Deputy for Business Support, or the Account Managers must make a record of the Nonconformance. They send a written or electronic note to the individual responsible for corrective action of the existence of nonconformity relating to the action.

4.3 The person receiving the notice must conduct a root cause analysis and take corrective action and document. Depending on the nonconformance, they may also document a preventive action as outlined in 2QP14-01.

4.4 After implementation of corrective action, the person who implemented the corrective action must notify the person who initiated the nonconformity report. The Deputy for Business Operations, the Deputy for Business Management, the Deputy for Business Support, or the Account Managers, as appropriate, must verify the effectiveness of the

corrective action and document the closeout activities. USAMRAA implements rework and accept-as-is when correcting nonconformity.

4.5 Reworked contract files are always reinspected through the verification of corrective action process in order to make sure that the breach of procedure related to the contract file has been remedied. Reworked product shall be re-inspected in accordance with the documented procedures.

4.6 In the case of the rework of a nonconformity related to either a Federal regulation or USAMRAA's procedures and instructions, the nature of the rework must be documented and is included as part of the hardcopy or electronic contract file.

5.0 RELATED DOCUMENTATION

Quality Manual Element 4.13
Corrective and Preventive Action – 2QP14-01
Master List of Quality Records
Document Master List

2QP14-01
CORRECTIVE AND PREVENTIVE ACTION

1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Element 4.14 of ISO 9002: 1994 Edition – CORRECTIVE AND PREVENTATIVE ACTION.

2.0 RESPONSIBILITY AND AUTHORITY

The Director, Deputy for Business Operations, the Deputy for Business Management, and the Deputy for Business Support have the responsibility and authority for implementing the requirements of this procedure.

3.0 PROCEDURE

3.1 When a complaint or concern is received, it is forwarded to the Director, Deputy for Business Management, the Deputy for Business Operations, or the Deputy for Business Support. The Director, the Deputy for Business Management, the Deputy for Business Operations, or the Deputy for Business Support retain the right to distinguish a valid customer complaint from one that stems from the customer's misunderstanding of their own requirements or unreasonable expectations.

3.2 The Director, the Deputy for Business Operations, the Deputy for Business Management, or the Deputy for Business Support are responsible for the follow-up of corrective action to make sure that the corrective action that was documented is, indeed, effective. The results will be documented and tracked in the Task Management System by the relative Tasker Number, Action Officer or Task Title.

3.3 The Director, the Deputy for Business Operations, the Deputy for Business Management, or the Deputy for Business Support are responsible for monitoring the timeliness of assigned corrective actions. The Director, the Deputy for Business Management, the Deputy for Business Operations, and the Deputy for Business Support run reports for the corrective action that they assigned and the corrective actions for which their respective divisions are responsible**.** A search may be executed with the "Find" button by selecting the relative Tasker Number or Action Officer or Task Title.

Preventive Action

3.4 A preventative action process has been developed to detect potential non-conformities or to fix an observation before it becomes a non-conformity. The sources for this information are the Procurement Management Reviews (PMR), SPS, Extramural Research Management System (ERMS), Task Management System and review of previous Internal Audit Reports, customer complaints, customer surveys and quality records. The documented procedures controlling aspects of preventive action are as follows:

- Appropriate sources of information mentioned above to detect, analyze and eliminate potential causes of nonconformity are utilized.
- Determinations of appropriate steps to be taken to prevent nonconforming situations are established depending on the situation.
- The preventive actions are initiated, tracked and effectively implemented through the Tasker System
- Preventive actions are reported at Management Review Meetings.
- The MR maintains records associated with preventive action.

Reporting

3.5 The Deputy for Business Management/MR is responsible for reporting corrective and preventive actions at Management Review Meetings. Summary reports may be taken from the electronic system to facilitate this reporting.

5.0 RELATED DOCUMENTATION

Quality Manual Element 4.14
Master List of Quality Records
Document Master List
Task Management System (Electronic)

2QP15-01
HANDLING, STORAGE, PACKAGING, PRESERVATION, AND DELIVERY

1.0 PURPOSE

This procedure complies with the requirements of Element 4.15 of ISO 9002: 1994 Edition – HANDLING, STORAGE, PACKAGING, PRESERVATION AND DELIVERY.

2.0 RESPONSIBILITY AND AUTHORITY

The Account Managers, Branch Chief, and Contract Specialists have the responsibility and authority for implementing the requirements of this procedure. The Chief Information Officer has the responsibility to support and maintain all electronic systems and backup systems require for implementation.

3.0 PROCEDURE

Handling

3.1 The Branch Chief, Account Managers and contract specialists ensure that hard copy contract files are handled with the utmost of care. Total electronic system files are backed up on a daily basis by the Information Management Office staff.

Storage

3.2 Contract files exist in either hard copy or electronic format or both. Hardcopy contract files are stored in file folders or binders and are kept in an environment that ensures their integrity for use. Electronic files are stored on official electronic media.

Packaging

3.3 Hard copy files are labeled with the PIIN number and other identification according to the MARKS system. Electronic files are labeled with just the PIIN number but this PIIN can be traced to all other information.

Preservation

3.4 There are no special preservation issues associated with the contract files. Appropriate storage conditions are maintained for hard copy files, and total electronic system files are backed up on a daily basis.

Delivery

3.5 Delivery of contracts is accomplished by mailing of hardcopies to the customers. Electronic version is resident within SPS.

4.0 RELATED DOCUMENTATION

Quality Manual Element 4.15
Master List of Quality Records
Document Master List
Work Instructions/Regulations (FAR, DFARS, AFARS, DODGAR, AI)
SPS Manual (Appendix C)

2QP16-01

CONTROL OF QUALITY RECORDS

1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Element 4.16 of ISO 9002: 1994 Edition – CONTROL OF QUALITY RECORDS.

2.0 RESPONSIBILITY AND AUTHORITY

The Deputy for Business Management/ MR and Deputy for Business Operations have the responsibility and authority for implementing the requirements of this procedure.

3.0 PROCEDURE

3.1 USAMRAA maintains the quality records mandated by ISO 9002: 1994 that are applicable to its operations. The Master List of Quality Records clearly details which record-keeping requirements are applicable including the record storage locations and the record retention periods.

3.2 Hard copies of quality records are stored in a manner that prevents damage, deterioration, or loss. The preferred storage method involves the use of file folders or binders.

3.3 The storage location that is listed on the Master List of Quality Records ensures that all quality records are easily retrievable and accessible to all necessary individuals. Contracting records are retained in accordance with MARKS System and FAR, depending on the type of contract. When space constraints are an issue then other hard copy records are stored off-site.

3.4 All hard copy records are clearly labeled to facilitate identification, indexing, and filing. The Army's MARKS system is used for labeling all official files.

3.5 All personnel are responsible for ensuring legibility of hard copy quality records. Records are made available for inspection to customers on request.

3.6 Some quality records are stored electronically. Electronic back-ups are made daily to tape. These tapes are stored off site.

3.7 Designated closeout personnel are responsible for the destruction of quality records when their retention periods expire or taking these documents to the archive facility.

4.0 RELATED DOCUMENTATION

Quality Manual Element 4.16
Master List of Quality Records
Document Master List

2QP17-01
INTERNAL QUALITY AUDITS

1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Element 4.17 of ISO 9002: 1994 Edition – INTERNAL QUALITY AUDITS.

2.0 RESPONSIBILITY AND AUTHORITY

The Deputy for Business Management/ MR, the Lead Auditor, and the Internal Quality Audit Team have the responsibility and authority for implementing the requirements of this procedure.

3.0 PROCEDURE

3.1 Deputy for Business Management/ MR schedules internal quality audits on the basis of the status and importance of the activity to be audited. Deputy for Business Management/ MR may choose to refer to the results of previous internal audits and the results of previous third party audits in order to schedule future internal quality audits. Thus, the audit schedule is a working document that is updated as necessary. The Deputy for Business Management/ MR does ensure that all ISO 9002: 1994 elements are audited at least once a year.

3.2 All auditors have been trained in the ISO 9002: 1994 Standard by a qualified training contractor and are knowledgeable about basic audit theory. The Director then appoints auditors. The MR maintains copies of auditor appointments and training certificates. Auditors gather objective evidence through the following techniques: interviewing employees, reviewing documents, reviewing records, and observing activities and or processes.

3.3 In scheduling the audits, the Deputy for Business Management/ MR ensures that personnel independent of those having direct responsibility for the activity being audited carry out internal quality audits.

3.4 The Deputy for Business Management/ MR notifies the Deputies and Branch Chiefs of areas scheduled to be audited one week prior to the audit.

3.5 The selected members of the Internal Quality Audit Team use the USAMRAA Internal Quality Audit Checklist and the USAMRAA Internal

Quality Audit Nonconformance/Observation report to record the audit findings.

3.6 At the conclusion of the audit, a closing meeting will be held to bring the audit findings to the attention of management personnel responsible.

3.7 If management disagrees with an audit finding, they may present evidence to the contrary to the Lead Auditor during the closing meeting. The Lead Auditor will review the objective evidence given, and make a final determination.

3.8 If it is determined that corrective action is needed, the auditee then has thirty days to decide upon the appropriate corrective action and a date by which the corrective action will be implemented. The suggested corrective action is recorded on the Internal Quality Audit Nonconformance Observation Report and is submitted to the Lead Auditor for approval.

3.9 If the Lead Auditor accepts the suggested corrective action, then the auditee must implement it within the agreed to time period. If the Lead Auditor does not think that the corrective action is sufficient, then the auditee will have one additional week to devise an alternate corrective action. If the auditee requires additional time for implementing the corrective action, then they must gain permission from the Lead Auditor.

3.10 At the start of each audit the Lead Auditor is responsible for reviewing the Corrective Action Log for outstanding corrective actions and must follow-up on these as part of the regularly scheduled audit.

3.11 The next scheduled audit must then verify the implementation and effectiveness of corrective actions, as appropriate. At the start of each audit the Lead Auditor is responsible for reviewing the Corrective Action Log for outstanding corrective actions and must follow-up on these in addition to the regularly scheduled audit. Follow-up activities are recorded on the Internal Quality Audit Nonconformance/Observation Report. In order to complete the closeout process, the Lead Auditor must sign the Internal Quality Audit Nonconformance/Observation Report and enter the closeout date in the Corrective Action Log.

3.12 The MR must present the results of all internal quality audits at the next Management Review Meeting.

4.0 RELATED DOCUMENTATION

Quality Manual Element 4.17
Corrective and Preventive Action Procedure, 2QP14-01
Master List of Quality Records
Document Master List

2QP18-01
TRAINING

1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Element 4.18 of ISO 9002: 1994 Edition -TRAINING.

2.0 RESPONSIBILITY AND AUTHORITY

The Director, the Deputy for Business Management, the Deputy for Business Support, and the Branch Chiefs have the responsibility and authority for implementing the requirements of this procedure.

3.0 PROCEDURE

3.1 Training requirements are very specific for acquisition positions. The Department of Defense (DoD) and the Department of the Army (DA) spell out these requirements. The Defense Acquisition University (DAU) publishes a list of training requirements each year for every career program as part of their catalog. The Branch Chief is responsible for monitoring all training requirements against the current mandatory standards.

3.2 Level 1 Certification is for people just entering their CAREER PROGRAM. They've taken the basic courses and have 1-2 year's experience in their field.

Level 2 Certification is the intermediate level. Advanced topics related to the primary career field are covered.

Level 3 Certification is the advanced level. All professional courses have been completed. Four positions at USAMRAA have been identified as Acquisition Corp positions. All must be Level 3 certified. This requires a detailed application procedure and independent review. All four positions are currently filled with qualified personnel.

3.3 Each employee maintains his/her own record of all the training they have received. Included in this may be copies of degrees, diplomas, and certificates earned. The individual employees are responsible for keeping track of the continuous learning points that they earn. The employees are responsible for informing their supervisor of any training that has been received through the use of the IDP. The employee maintains his/her own

Career Record Brief which is filed and maintained within an Acquisition Army-wide database.

3.4 An internal training program for interns requires DAU courses and a rotation through all divisions. The Branch Chiefs, assigned as mentors monitor those interns in this program. There is a checklist of objectives to be accomplished for each branch along with a timeline. The Branch Chief is required to sign off on all training.

4.0 RELATED DOCUMENTATION

Quality Manual Element 4.18
Master List of Quality Records
Document Master List
Training Matrix Form

2QP20-01
STATISTICAL TECHNIQUES

1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Element 4.20 of ISO 9002: 1994 Edition – STATISTICAL TECHNIQUES.

2.0 RESPONSIBILITY AND AUTHORITY

The Deputy for Business Management and the Deputy for Business Operations have the responsibility and authority for implementing the requirements of this procedure.

3.0 PROCEDURE

3.1 Cost to Purchase Ratio, the Average obligations per person, and the average obligation per action are USAMRAA required applications for statistics. The data is also reported to the Army as required. for comparison to Army-wide statistics shown on the Army Homepage.

3.2 USAMRAA has also established goals for the percentage of contracts that are awarded as competitive.

3.3 The Department of Army also requires reporting the percentage of contracts that are awarded to small and disadvantaged businesses.

3.4 The responsible staff members analyze statistics related to this procedure. These are presented in the Executive and Staff Meetings as well. Corrective action is taken as needed in accordance with 2QP14-01.

4.0 RELATED DOCUMENTATION

Quality Manual Element 4.20
Master List of Quality Records
Document Master List